510(k) SUMMARY

JAN - 7 2011

Prepared:	December 14, 2010
Submitter:	Reprocessing Products Corporation
Address:	3655 N. Oracle Road Tucson, AZ 85705
Phone:	520-888-5551
Fax:	(Fax) 520-888-5557
Contact:	Michael Honstein, Chief Operating Officer
Device Trade Name:	Two ranges: 0-14 pH Test Strips (K100-0104) and 6.8-8.5 pH Test Strips (K100-0117)
Common or Usual Name:	pH Test Strips
Device Classification Name:	Strip, Test, Reagent, Dialysate, Water
Product Code:	MSY
Class:	II
Regulation Number:	876.5665
Substantial Equivalence:	The Reprocessing Products Corporation pH Test Strips are substantially equivalent to the SERIM® BICARB PH REAGENT STRIPS
Device Description:	Device is semi-quantitative, reagent test strip comprised of a pad impregnated with chemicals which change color upon contact with Dialysate or Water respectively. The pad is attached to a plastic strip for handling.
Intended Use:	The Reprocessing Products Corporation Test Strips are intended for use in the monitoring of pH in Dialysate and Water.
Technological Characteristics:	pH test strips are comprised of two different pH ranges: The K100-0117 test Strips will determine the pH in the range of 6.8 -8.5 for acid/bicarbonate dialysate, bicarbonate concentrate and water used to prepare dialysate. The K100-0104 test strips will determine the in the range of 0-14 pH for water used to prepare dialysate. The test strip contains a specialized chemical formulation that reacts with the Hydrogen ion concentration in solutions of dialysate and water. The reaction results in a color change which is correlatable to the concentration of Hydrogen ions in the

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	solution. The color change is interpreted by the use of color blocks on two separate (ranges) color charts. Gradations for 6.8-8.5 pH Test Strips (K100-0117) include 6.8, 7.0, 7.2, 7.4, 7.6, 7.8, 8.0, and 8.5. Gradations for the 0-14 pH test strips (K100-0104) include 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, and 14.
Performance:	The data confirm that the product consistently generates color changes which match the color blocks for the Reference solution pH. Reference solutions were used to evaluate pH performance between 6.8 and 8.5 in acid/bicarbonate dialysate, bicarbonate concentrate and water, and the pH performance between 0 and 14 in water used to prepare dialysate. These data demonstrate appropriate performance for use in hemodialysis dialysate and water.
Conclusion:	The Reprocessing Products Corporation pH test strips have the same intended use as the predicate device. Test strips measure the hydrogen ion concentration in acid/bicarbonate dialysate or water. The Reprocessing Products Corporation pH Test Strips have no characteristics which raise new types of safety and effectiveness questions. The Reprocessing Products Corporation pH Test Strips can be used to monitor the pH (hydrogen ion concentration) present in water and/or dialysate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

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Reprocessing Products Corp.
c/o Mr. Walter B. Jansen
MedReg Consulting
8662 Comstock Lane N.
MAPLE GROVE MN 55311-1436

Re: K101750
Trade/Device Name: RPC E-Z CHEK® pH TEST STRIPS
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: MNV
Dated: January 5, 2011
Received: January 5, 2011

Dear Mr. Jansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Statement of Indications for Use:

Indications for Use

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510(k) Number (if known): K101750

Device Name: RPC E-Z CHEK® pH TEST STRIPS

Indications for Use: The Reprocessing Product Corporation (RPC) pH Test Strips are indicated for determining the pH of acid dialysates, bicarbonate dialysates, or water. These Test Strips are indicated for testing acid/bicarbonate dialysates and water.

- pH Test Strips are comprised of two different pH ranges:
  - pH = 6.8-8.5 (K100-0117) is for acid/bicarbonate dialysate, bicarbonate concentrate and water
  - pH = 0-14 (K100-0104) is for water used to make up dialysate.

Prescription Use _____X_____ AND/OR Over the Counter Use _____
(Part 21 CFR 801 Subpart D) (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K101750